### **DETAILED ACTION**

This action is in response to the applicant's amendment received 17 November 2010. Claims 1-29, 34, 40, 46, 59, 98, 99, 101, and 102 remain cancelled. The application is not in condition for allowance for the reasons set forth below.

#### Terminal Disclaimer

The terminal disclaimer filed on 17 November 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,740,640 has been reviewed and is NOT accepted. The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). NOTE: The power of attorney may name those registered patent practitioners associated with the Customer Number. However, the power of attorney must be in writing and the office will not recognize more than ten patent practitioners as being of record in an application.

### Response to Arguments

The amendments made to claim 94 overcome the previous objection and have been accepted.

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Applicant's arguments filed 17 November 2010 with respect to the 112 rejection have been fully considered and are persuasive. The 112 rejection of claims 30-33, 35-39, 41-45, 47-58, 60-97, 100, and 103-106 has been withdrawn.

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## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-33, 35-39, 41-45, 47-58, 60-97, 100, and 103-106 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-100 of U.S. Patent No. 7,740,640 B2 in view of Oman et al. (U.S. Patent No. 7,288,105 B2).

The claims of the copending application also recite a method of closing a patent foramen ovale by situating a clip through overlapping tissue flaps to close a tunnel

therebetween. The co-pending application fails to recite an implantable device as recited in the instant application.

Oman discloses a method for treating a patent foramen ovale (see entire document) comprising the steps of advancing an implantable device (30) through the vasculature of a subject within an elongate delivery apparatus (a catheter; for example, see column 9, lines 25-27) and situating, engaging, and releasing the implantable device within piercings of overlapping first and second tissue flaps defining a tunnel (piercing is formed by the needle-like tips of the filament 40 of the implantable device which penetrate the tissue), wherein a first elongate portion of the device (end of 40 in left atrial chamber) engages the first tissue flap and is exposed in a second (left) atrial chamber, a second elongate portion of the device (end of 40 in left atrial chamber or vice versa - see claim 62) engages the second tissue flap and is exposed in a first (right) atrial chamber, an intermediate portion of the device lies between the first and second portions (see below for details on the composition on the first and second portions in which the intermediate portion lies between the defined boundaries), and the first and second elongate portions may be considered to be made up of a first end (passed through the tissue flap in chambers), intermediate region (portions within the tissue flaps), and second end (a portion of segment within the tunnel formed by the flaps and panel portion 32 or vice versa in which the first portion would comprise a portion lying substantially perpendicular to a longitudinal axis of a portion within the first piercing as recited in claim 42) all pivotally coupled in that the entire portion (40) is formed of a spring material and thus any portion may pivot relative to the other to retain

the tissue flaps (for example, see Figure 24 for illustration). Oman further disclose the steps of deploying the biased device from the elongate delivery apparatus such that it transforms, pivots, or transitions to a retaining configuration (for example, see Figure 24 and column 9, lines 25-31), securing the second portion to the device to retain the second portion against the second tissue flap (for example, see Figure 24), the second portion includes retaining arms or laterally extending members (opposing portions of panel 32 defined by support structure 36) capable of engaging and retaining the second tissue flap as they lie substantially in a plane parallel to the second tissue flap and thus may be considered "locking elements" that lockingly engages the filament ( or wire "suture" 40), the device may comprise NITINOL or other shape memory material (for example, see column 8, lines 20-32), and the first portion (for example, portion 32 of the device) resides substantially flat against the first tissue flap in the retaining configuration (in order to fully contact the tissue; for example, see column 7, lines 39-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the clip in '493 application with the implantable device taught by Oman since the substitution of one known element for another would have yielded predictable results, namely, providing an effective means for closing a patent foramen ovale.

# Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest, in combination with other limitations in the claims, the first and second tissue flaps are engaged such that the first flap is held in

contact with the second tissue flap to close the tunnel and the tunnel therebetween is closed.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571) 272-9062 and e-mail address is melanie.tyson@uspto.gov. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/ Primary Examiner, Art Unit 3773 January 19, 2011